K094048

510(k) Summary

JUL 14 2011

As required by section 807.92(c)

Company Name	Cardiosolutions Inc.
Address	75 Mill St. Stoughton, MA 02072 Phone: 781-344-0801 Fax: 781-344-0803
Contact Person	Michele Lucey
Date Prepared	May 10, 2011
Trade Name	Percu-Pro™ Messenger Balloon Catheter
Common Name	Intravascular Guiding Catheter
Classification Name	Flow-Directed Catheter
Product Code	DYG
Regulation #	21 CFR 870.1240
Class	2
Panel	Circulatory System Devices Panel
Predicate Devices	TechDevice Percutaneous Occlusion Balloon Catheter K051137 Boston Scientific Schneider Guider™ Softip™ Guiding Catheter K961999, K010853 Biosensors International Flow Directed Thermodilution Catheter K083384
Device Description	The Cardiosolutions Percu-Pro™ Messenger Balloon Catheter is a 5Fr catheter with a bifurcated proximal hub. The catheter shaft and connection ends are made from Pebax and the distal tip balloon is made from latex.
Intended Use	The Percu-Pro™ Messenger Balloon Catheter is intended to facilitate the placement of interventional devices during diagnostic and interventional cardiovascular procedures. The device is not intended for coronary or neurovascular use.
Safety and Performance Testing	No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices, However, testing was conducted in accordance with protocols based on the requirements of industry standards and FDA Guidance documents. Non-clinical testing included: biocompatibility; catheter tensile strength; balloon bond tensile strength; multiple inflation to burst; marker band adherence; and Insertion and withdrawal force testing.

Substantial Equivalence	The Percu-Pro™ Messenger Balloon Catheter is identical in design to the TechDevice Occlusion Balloon Catheter K051137 with the exception of the platinum-iridium marker bands that are contained in the Percu-Pro Device but not in the TechDevice. By identical we mean that the Percu-Pro device is made from the same materials, is specified by the same design, and is manufactured by the same processes used for the TechDevice Occlusion Balloon Catheter. These marker bands have been added because they are radiopague and are useful for viewing the position of the catheter during insertion and manipulation. The Percu-Pro™ Messenger Balloon Catheter has the same intended use as the Boston Scientific Schneider™ Softip™ Guiding Catheter(K961999), is made from similar materials, and is similar in length and diameter. Both devices have multi-lumen to allow for insertion of a guide wire to permit access for other devices. The Boston Scientific device is provided with multiple distal tip designs with varying stiffnesses to accommodate different uses, the Percu-Pro™ device is offered in only one configuration. Based upon a significant history of use for the same purpose in the same area of the body new questions regarding safety are not raised. The Percu-Pro™ Messenger Balloon Catheter incorporates an inflatable balloon tip to allow for flow direction for catheter tip positioning. This intended use and design feature are substantially equivalent to the Biosensors Thermodilution Catheter (K083384) which defines a balloon tip to allow for flow direction for catheter tip positioning in their intended use statement by means of an inflatable balloon tip. The Percu-Pro™ Messenger Balloon Catheter is substantially equivalent to the predicate devices in terms of intended use, design, materials, technology, and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Cardiosolutions, Inc.
c/o Michele Lucey
75 Mill Street
Stoughton, MA 02072

JUL 14 2011

Re: K094048
Trade/Device Name: Percu-Pro™ Messenger Balloon Catheter
Regulation Number: 21 CFR 870.1240
Regulation Name: Flow-directed catheter
Regulatory Class: Class II
Product Code: DYG
Dated: May 10, 2011
Received: May 12, 2011

Dear Ms. Lucey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Percu-Pro™ Messenger Balloon Catheter

Indications for Use:

The Percu-Pro™ Messenger Balloon Catheter is intended to facilitate the placement of interventional devices during diagnostic and interventional cardiovascular procedures. The device is not intended for coronary or neurovascular use.

Prescription Use ___X___ AND/OR Over-The_Counter Use_____

(PLEASE DO NOTR WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K094048